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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,011	12/04/2001	Renato V. Iozzo	IOZ01-NP009	7689

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/04/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/006,011

Applicant(s)

IOZZO, RENATO V.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 8/21/2003 (paper no. 12) is acknowledged and entered into the record. Accordingly, claim 16 is cancelled without prejudice or disclaimer and claim 17 is newly added.
2. Claims 1-15 and 17 are pending, claims 1-14 are withdrawn from further consideration as being drawn to a non-elected subject matter.
3. Claims 15 and 17 are examined on the merits.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 15 and now newly added claim 17 under 35 USC 112, 1st paragraph as lacking written description is maintained for the reasons of record. Applicant argues that fragments are fully disclosed and multiple examples are found within the specification so as to be enabled for the full scope of fragments. Applicant also argues that each and every fragment claimed under the broad recitation the term "fragment" does not need to be disclosed, as long as a representative number of fragments are disclosed in the specification so that one of skill in the art would know that the applicant was in possession of the claimed invention. Applicant's arguments have been carefully considered but are not found persuasive. Although the applicant has disclosed a number of examples of "fragment" corresponding to endorepellin or domain V of perican, one of skill in the art would not readily be able to screen for such fragments because there are numerous possible fragments that fall within the scope of the term "fragment", irregardless of whether or not the fragment actually retained functional activity. The claims do not reflect fragments which define a specific type of

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activity so as to be entitled to the broad recitation of any and all fragment of endorepellin. Furthermore, the claims as currently interpreted encompass more than the fragments of 3687-4391 or 3927-4181 and because the claims lack specific functional limitation associated with the fragments, this includes any combination of contiguous amino acids found within perican domain V. The seven fragments disclosed in figure 1f is therefore not representative of the "functional" fragments intended as the invention. As such, the fragments disclosed in the specification are not all encompassing and does not represent the full scope of the term "fragment", because the structure of the "fragment" is not known and the function of those fragments have not been claimed, so as to teach the skilled artisan that the applicant was in possession of fragments that are representative of the those fragments claimed.

Claim Rejections Maintained - 35 USC § 102

5. The rejection of claim 15 under 35 USC 102 (b) as being anticipated by Snow *et al* is maintained for the reasons of record. Applicant argues that each and every limitation of the claim must be taught in the prior art and that Snow *et al* is drawn to the use of perican and not of endorepellin for the treatment of amyloidosis problems. Applicant's arguments have been carefully considered but are not found persuasive. Snow *et al* teaches a pharmaceutical composition comprising perican or derivatives thereof. Endorepellin is equivalent to domain V of perican. The claims of the instant invention have not taught the exact structure of the claimed endorepellin fragments, and the use of the perican derivatives taught by Snow *et al* still anticipates the instantly claimed invention because the endorepellin fragments claimed cannot be distinguished

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over the derivatives of perlican disclosed in the prior art. Because the Patent Office does not have the facilities to prove otherwise, the burden of proof resides with the applicant to prove that the derivatives claimed by Snow *et al* do not include the endorepellin fragments claimed. The intended use of the claimed composition does not carry any patentable weight because the composition taught by Snow *et al* appears to be the same as that instantly claimed.

6. The rejection of claim 15 under 35 USC 102(b) as being anticipated by Whitelock *et al* is maintained for the reasons of record. Applicant's arguments are substantially the same as that made for Snow *et al* (*supra*). Endorepellin is equivalent to domain V of perlican. The claims of the instant invention have not taught the exact structure of the claimed endorepellin fragments, and the use of the perlican active fragments taught by Whitelock *et al* still anticipates the instantly claimed invention because the endorepellin fragments claimed cannot be distinguished over the active fragments of perlican disclosed in the prior art. Because the Patent Office does not have the facilities to determine otherwise, the burden of proof rests with the applicant to prove that the active fragments claimed by Whitelock *et al* do not include the endorepellin fragments claimed. The intended use of the claimed composition does not carry any patentable weight because the composition taught by Whitelock *et al* appears to be the same as that instantly claimed.

New Arguments

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instantly claimed invention is drawn to a pharmaceutical composition consisting of an amino acids 3687-4391 of endorepellin or an endorepellin fragment. The specification defines such endorepellin as that disclosed in Murdoch *et al* (J. Biol Chem. 267(12):8544-8557) (see reference #5 in the specification). It appears that the sequence taught by Murdoch *et al* is essential to the practice of the instant invention.

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Nonessential subject matter may be incorporated by reference to (1) patents or application published by the United states or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications or (3) non-patent publications, for purposes of indicating the background of the invention or illustrating the state of the art.

The referencing application must include (1) an abstract, (2) a brief summary of the invention, (3) an identification of the referenced patent or application, (4) at least one view in the drawing in those applications admitting of a drawing, and (5) one or more claims. Particular attention should be directed to specific portions of the referenced patent or application.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, the pharmaceutical composition

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claimed would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue

Applicant is reminded to provide said Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the essential subject of the "amino acid sequence" as set forth by Murdoch *et al.*

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedrich *et al* (J. Mol. Biol. 1999 294:259-270, applicant IDS BC) in view of Snow *et al* (previously cited). Claims are drawn to a pharmaceutical composition comprising endorepellin and a pharmaceutical carrier, wherein the endorepellin consists of amino acid residues 3687-4391 (claim 15) or amino acid residues 3687-4181 or 3927-4181 (claim 17).

Friedrich *et al* discloses both an amino acid sequence which appears to be identical to amino acids 3687-4391 and 3927-4181 (see page 260 1st paragraph and

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figure 1). Although the molecule is not characterized as “endorepellin”, endorepellin and domain V of perlican appear to be the same molecule. Furthermore, Friedrich *et al* do not specifically characterize the compound with a pharmaceutical carrier, it would be obvious to do so in view of the teachings of Snow *et al*.

Snow *et al* teach the use of biologically active perlican fragments in a pharmaceutical carrier (see column 15).

It would have been *prima facie* obvious to one of skill in the art at the time the invention was made to use fragments of domain V or endorepellin in a pharmaceutical carrier to be administered to a subject because it was taught that domain V and its fragments are involved in diverse biological functions ranging from being a strong ligand for α -dystroglycan to being a involved in β 1 integrin interaction. One of skill would have found motivation in combining the fragments of endorepellin with a pharmaceutical carrier because the fragments on their own showed biological activity when analyzed by Friedrich *et al* (see 260-265, and figure 7). The combination of two known products, in this case domain V and/or a fragment consisting of 3927-4181 with a pharmaceutical carrier is considered obvious absent any unexpected results.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 12.

Conclusion

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Christopher Yaen

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October 20, 2003


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